

REMARKS

1. This paper is responsive to the non-final Office Action mailed on September 4, 2007. Claims 1 to 30 are pending in this application and have been rejected. Applicants believe that no fee is due in connection with this Response, however, please charge Deposit Account No. 02-1818 for any fee deemed owed. Claims 1, 13 and 24 are amended to add missing conjunctions.

2. Claims 13-18, 20, 22, and 23 are rejected under 35 U.S.C. §102 (b) as being anticipated by Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). Claims 24-30 are also rejected under 35 U.S.C. §102 (b) as being anticipated by Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). Claims 1-2, and 5-12 are rejected under 35 U.S.C. §103 (a) as being unpatentable in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts et al."). Claims 3, 4, 19 and 21 are also rejected under 35 U.S.C. §103 (a) as being obvious in view of Roberts. Finally, Claim 15 is also rejected under 35 U.S.C. §103 (a) as being obvious in view of Roberts, and further in view of WO 99/06082, a PCT application to Joseph Dadson ("Dadson").

3. Claims 13-18, 20, 22, and 23 are rejected under 35 U.S.C. §102 (b) as being anticipated by Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). Applicants traverse the rejection, because the Office Action fails to show that Roberts teaches each limitation of at least Claim 13, from which Claims 14-18, 20 and 22-23 depend. In the rejection, the Office Action cites several passages and figures from Roberts.

A fluid loop configured to circulate dialysate . . . via only a single loop of the fluid loop

The rejection cites Roberts, col. 1, p. 377, second paragraph, disclosing a single loop that is a modification of the single fluid loop in the paragraph above and in Fig. 12 of Roberts. Office Action, p. 2, lines 17-19. Fig. 12 discloses a single loop that includes the catheter of Fig. 11 within the patient, and also includes a 20 liter bag of dialysate. The fluid loops from the bag, through an in-line heater, to a pump, into and out of the patient, and then through a one-way valve and back to the bag. A pressure sensor is between the catheter and the one-way valve.

This would constitute a fluid loop configured as shown in Fig. 12, with the fluid loop configured, as claimed, to circulate dialysate into, through, and out of a peritoneal cavity of the patient via only a single loop of the fluid loop. Fig. 12 also shows other items.

Per the rejection, this single fluid loop is modified as mentioned in the second paragraph on Roberts, p. 377. The modification mentioned is “an alternative flow-thru method” using fresh dialysate for inflow while the fluid in the peritoneum is recirculated at a high flow rate. The paragraph then states that there will be outflow of spent dialysate which is adjusted to the inflow. There is no teaching in either paragraph in col. 1 of p. 277 of where the outflow goes. Thus, as best Applicants understand the rejection, the Office Action asserts that Roberts depicts a single fluid loop as shown in Fig. 12, but instead of circulating the dialysate between the patient and the bag, the dialysate flows into the patient, loops within the patient (“the fluid in the peritoneum is recirculated at a high rate”), and then flows out. The paragraph concludes by stating that no patients have ever been maintained on this “flow-thru PD.” Thus, according to the Office Action, the single loop of the fluid circuit includes the dialysate bag, the pump, the catheter, and an outflow from the catheter. The outflow is not further discussed on p. 377 or shown in Fig. 12.

Using this analysis, we proceed to the claim limitation of a chamber. The rejection states that this limitation is met by filter A in Fig. 7, p. 375. Fig. 7 depicts Filter “A” situated outside the patient, the figure appearing to depict a flow of dialysate **in** at the top right, “C” and ultrafiltrate UF **out** at the lower right (emphases added). The rejection states that dialysate flows to and from the patient and to and from filter A at some unspecified feed rate. Office Action, p. 3, lines 3-7. This is a fluid loop and Fig. 7 depicts the loop, which includes the filter, the patient, and the connecting lines between them. However, per the above paragraph, we already have a first or outer fluid loop, with the filter or chamber forming a second or inner loop. Thus, the rejection cites a fluid circuit with two loops, not a single loop: the first loop formed by the dialysate bag, the pump, and the outflow, and the second loop within the first loop, including the filter, each loop forming a fluid loop and connecting to the catheter. Since there are two loops, this construction does not meet the Claim 13 limitation of a fluid circuit having only a single loop, because there are two loops, one within the patient and one outside the patient.

Even if this construction did not teach two loops, Fig. 12 of Roberts also teaches additional elements as part of his system, such as the pressure gauge and one-way valve of Fig,

12 and the filter of Fig. 7. The alternative flow-through method does not remove the pressure gauge and the one-way valve. Using the filter as a chamber does not remove its filtering function. The Claim 13 preamble, “consisting of” excludes any element not specified in the claim. When this preamble appears in a clause of the body of a claim, it limits only the element set forth in that clause, but does not limit other elements from the claim as a whole. M.P.E.P. 2111.03. Claim 13 has only two elements, a catheter and a fluid circuit, with the preamble applying to the fluid circuit. Accordingly, when any of the pressure gauge, the one-way valve, and the filter in Figs. 7 and 12 are added to the alternate flow-through method of p. 377, the result is inconsistent with at least the “consisting of” portion of the claimed fluid circuit. Accordingly, the reference does not teach, or even suggest, Claim 13 as recited.

Dependent claims

The rejection also fails to make out a prima facie case of anticipation for several of the claims depending from Claim 13. For example, Claim 17 recites that the chamber is capable of heating and mixing the dialysate, and the Office Action cites the filter of Fig. 7 as the chamber, and Fig. 12, which discloses a heater. However, the in-line heater of Fig. 12 is clearly separate from and outside any chamber, and thus Roberts does not disclose the claim limitation of “a chamber capable of mixing and heating the dialysate.” Furthermore, while a filter housing could conceivably be interpreted as a chamber, there is no suggestion that a filter can also perform the function of a mixer.

During prosecution, claim term may be interpreted broadly, but the interpretation must still be reasonable. M.P.E.P. 2111. *See also, e.g., In re Buszard*, No. 2006-1489, slip op. at 6 (Fed. Cir. Sept. 27, 2007) (rejecting a claim interpretation that the term “flexible foam” included rigid foam that had been crushed into tiny particles because this is not the way a person of skill in the art would interpret the term “flexible foam”). The filter of Fig. 7 is used, as stated by Roberts on p. 374, to separate dialysate from ultrafiltrate, not to mix them. The Office Action admits that filter 7 functions as a filter, removing particles, but with no teaching of a mixing function, and a filter or filter housing cannot reasonably be interpreted as a mixer. *See Office Action*, p. 6, lines 3-7. Accordingly, Roberts does not teach the limitations of Claim 17.

Claim 23 likewise is also not anticipated. The rejection, citing Fig. 7 and p. 374, col. 2, paragraph 2, states that filter A in Fig. 7 is a chamber, and that the chamber is in communication

with the fluid loop which can accommodate a variable increase in the dialysate during treatment and that the increase is due to an addition of ultrafiltrate to the fluid loop. Whether this is correct or not, the rejection does not assert, and does not show, that the chamber can be adapted to accommodate a variable increase in the dialysate, as specified in the claim. Filter A is not described other than as a filter, and there is no teaching that it can accommodate any increase, let alone a variable increase as claimed. Claim 23 is therefore allowable as claimed.

4. Claims 24-30 are also rejected under 35 U.S.C. §102 (b) as being anticipated by Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). The office action cites Roberts, and uses the dual-lumen catheter and the modified fluid loop discussed above for Claim 13. The pump in Fig. 12 of Roberts is also cited as the "cycler," and the filter of Fig. 7 is cited as the cleaning device.

By the same reasoning used above for Claim 13, this construction does not teach the Claim 24 requirement of a fluid circuit that defines only a single fluid loop. This construction makes a first loop with the dialysate bag, the cycler, the catheter, and an outflow of the spent peritoneal dialysate, along with associated tubing. The addition of the filter of Fig. 7, however, adds an additional loop, an additional inner loop that includes the filter outlet (whether nearer to the patient than the pump or farther), tubing to the catheter, tubing from the catheter, and the inlet to the filter. Claim 24 is therefore also not anticipated and is allowable. Claims 25-30 depend from Claim 24 and are also allowable.

5. Claims 1-2, and 5-12 are rejected under 35 U.S.C. §103 (a) as being unpatentable in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts et al."). The portion of the Office Action for Claim 1 follows the rejection arguments discussed above for Claims 13 and 24. Claim 1 is not obvious and therefore unpatentable, however, because as admitted in the Office Action, p. 10, lines 4-6, Roberts does not teach or suggest the Claim 1 limitation of a chamber coupled to the fluid loop, a chamber through which dialysate can be fed at a feed rate into the fluid loop. The limitation of a discharge fluid path is also not taught or suggested in Roberts.

The rejection cites Roberts, Fig. 6, as teaching the claimed chamber. The full claim limitation is "a chamber coupled to the fluid loop through with the dialysate can be fed at a feed rate into the fluid loop." This clearly requires that dialysate feeds into the fluid loop, not merely cycle the fluid that is already in the fluid loop (emphasis added). The bubble trap of Fig. 6 is clearly in the fluid loop and does not couple to the fluid loop to feed dialysate into the fluid loop.

In addition, the rejection also cites Roberts, p. 377, in which Roberts states that the outflow of the spent peritoneal dialysate would be adjusted to the inflow. There is no teaching, however, of an outflow other than the outflow back to the 20 liter bag disclosed in Fig. 12. Rather than the claimed discharge fluid path, the spent dialysate could just as well be cycled to a chamber or a filter. In any event there is no teaching or suggestion of a discharge fluid path nor of a chamber coupled to the fluid loop, as claimed. For these reasons, Claim 1 is not obvious in view of Roberts, and is therefore patentable.

Roberts also does not teach or suggest at least the limitations of dependent Claims 10-12. Claims 10 and 11 are allowable for the reasons discussed above for Claim 23. Claim 12 is allowable because the cited passage from Roberts, p. 377, col. 1, paragraph 2, contains no mention of alternately varying feed and discharge rates to create tidal CFRD. The cited paragraph states only that there is an alternate flow-through method (other than the method in Roberts paragraph 1) and that the outflow should be adjusted to the inflow, which is the opposite of the invention recited in Claim 12.

6. Claims 3, 4, 19 and 21 are also rejected under 35 U.S.C. § 103 (a) as being obvious in view of Roberts. The Office Action admits that Roberts does not teach the limitations of these claims, but that these involve only routine skill in the art. Office Action, p. 13, lines 5-9. Applicants traverse the rejections. In order to make out a prima facie rejection for obviousness, the reference must teach or suggest all the limitations of the claims. The rejection admits that Roberts teaches circulation ratios very different from those of Claims 3 and 4, and does not state how it arrived at the conclusion that these claims were arrived at with only routine skill in the art. If there is information to this effect that known to the Office, Applicants request the information be put on the record. In any event, Claims 3, 4, 19, and 21 are allowable at least because there is no prima facie rejection and because they depend from allowable claims 1 and 13.

7. Claim 15 is also rejected under 35 U.S.C. §103 (a) as being obvious in view of Roberts, and further in view of WO 99/06082, a PCT application to Joseph Dadson ("Dadson"). Claim 15 is allowable at least because it depends from allowable Claim 13.

8. Applicants submit that the claims are in condition for allowance, and respectfully request issuance of a Notice of Allowance. If the Examiner believes that a telephone conversation would expedite prosecution in this case, or would be of use to the Examiner, she is respectfully requested to call the undersigned.

Respectfully submitted,

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